IN THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

J. Gregor Sutcliffe RECEIVED Applicant:

Serial No.: 08/116.873

Attorney Docket JUL 2 2 1996 SCRF 32.0 DIV II 3181/58687

PATENT

Filed:

September 3, 1993 GROUP 1800

roup Art Unit 1813

SYNTHETIC POLYPEPTIDES CORRESPONDING For:

TO PORTIONS OF PROTEINOIDS

TRANSLATED FROM BRAIN-SPECIFIC mRNAs.

RECEPTORS, METHODS AND DIAGNOSTICS

USING THE SAME

Examiner:

L. Schriener

Assistant Commissioner for Patents Washington, D.C. 20231 Sir:

This Reply Brief is provided to assist the Board in further assessing the issues of this appeal, particularly in light of the Answer's newly applied reliance upon Amgen v. Chuqai, 19 USPQ2d 1017 (Fed. Cir. 1991), hereinafter Amgen, and assertions as to a lack of a recitation of function of a claimed DNA.

The Amgen decision portion with which the Answer has concerned itself has to do with conception of a DNA sequence that encoded the protein erythropoietin (EPO). EPO is a red blood cell-stimulating protein that is 165 amino acid residues in length.

As is well known, the genetic code is largely redundant, with there being at least two DNA codons that encode most of the amino acid residues. Some amino acid residues are encoded by six different codons, e.g. serine, arginine and leucine. Others such as valine and alanine are encoded by four condons, whereas still other residues are encoded by only one condon, e.g., methionine and tryptophan.

Although there are many more amino acid residues encoded by more than two codons than there are residues encoded by one codon, a very conservative estimate of an average of two codons per residue can be made. Using that very conservative estimate, it is easily seen that the number of DNAs that could encode the same EPO molecule is equal to 2¹⁶⁵. It is submitted that 2¹⁶⁵ is such an unimaginably large number that that number of separate EPO-encoding DNAs cannot be conceived of by an inventor, as was found by the Court in Amgen.

The parallel from <u>Amgen</u> to the present situation does not, however, follow. The present claims are not directed to any DNA that encodes a specific product as in <u>Amgen</u>. Rather, these claims are directed to <u>the specific gene that encodes a specific product</u> in a given mammal.

That number of genes can be conceived of. The application teaches how to obtain those genes. The art of record shows that others of skill in this art have understood the language used here and have been able to obtain their own genes, while reporting that they have relied-on Dr. Sutcliffe's published dicslosures that are present in this application.

The Answer also asserts that the functions of the DNAs (or mRNAs) as claimed have not been set forth. Counsel's review of each of the independent claims on appeal indicates that each DNA is recited to be "complementary" to a messenger RNA, and that that messenger RNA "encodes" a material that is "neuroactive". It is submitted that no further function is needed in a claim. Indeed, one does not look to the claims to find out how to practice the invention, but to the specification. In re Johnson and Farnham, 194 USPQ 187, 195 (CCPA 1977). The art of record

and that offered provide ample evidence that skilled workers understand the function of the DNAs of these claims.

It is therefore again submitted that these rejections should be reversed.

Respectfully submitted,

Edward P. Gamson, Reg. No. 29,381

Enclosure

Request for Oral Hearing and Fee

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CERTIFICATE OF MAILING

I hereby certify that this Appellant's Reply Brief on Appeal, in triplicate, and Request for Oral Hearing are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on June 26, 1996.

Edward P. Gamson